



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

April 17, 2002

**VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED**

In reply refer to Warning Letter SEA 02-42

Kenneth M. Van Dyke, President
Van Dyke Grain Elevators, Inc.
485 Main
North Plains, Oregon 97133

WARNING LETTER

Dear Mr. Van Dyke:

An inspection at your feed mill and lamb meal blending operation located at 485 Main, North Plains, Oregon, conducted by a Food and Drug Administration investigator on February 27-28, 2002, found significant deviations from the requirements set forth in Title 21, Code of Federal Regulations, Part 589.2000 - Animal Proteins Prohibited in Ruminant Feed. This regulation is intended to prevent the establishment and amplification of Bovine Spongiform Encephalopathy (BSE). Such deviations cause products being manufactured and distributed by your facility to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act).

Our investigation found that you failed to maintain sufficient written procedures and provide for measures to prevent cross contamination [21 CFR 589.2000] in that:

1. Written procedures are not maintained to specify the procedures for separating feed containing prohibited animal proteins from feed intended for ruminants from the time of receipt to the time of shipment [21 CFR 589.2000(e)(iv)].
 - You have no written procedures for keeping lamb meal, a prohibited material, separated from fish meal, an animal feed ingredient intended for ruminants.
2. You have not provided for measures to prevent commingling or cross-contamination between feed containing prohibited animal proteins from feed intended for ruminants [21 CFR 589.2000(e)(iii)].
 - The partial wall installed on February 28, 2002, does not completely separate the lamb meal, a prohibited material, from the fish meal, an animal feed ingredient.

Kenneth M. Van Dyke, President
Van Dyke Grain Elevators, Inc., North Plains, OR
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- There are no measures taken to prevent cross contamination from foot traffic between the area where prohibited material is stored on the floor and ingredients used in ruminant feeds. You are storing lamb meal, a prohibited material, directly on the floor within twenty feet from the area where you store fish meal directly on the floor. Employees walk back and forth between the two areas where these products are stored.

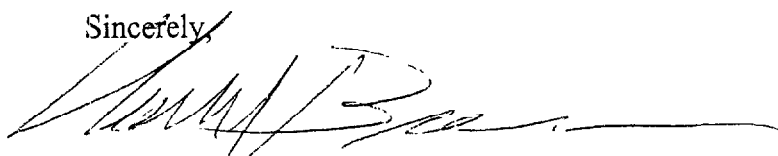
The above is not intended to be an all-inclusive list of deficiencies at your facility. As a manufacturer of materials intended for animal feed use, you are responsible for assuring that your overall operation and the products you manufacture and distribute are in compliance with the law.

You should take prompt action to correct these violations, and you should establish a system whereby such violations do not recur. Failure to promptly correct these violations may result in regulatory action without further notice, such as seizure and/or injunction.

You should notify this office in writing within fifteen (15) working days of receipt of this letter of the steps you have taken to bring your firm into compliance with the law. Your response should include an explanation of each step being taken to correct the violations, and prevent their recurrence. If corrective action cannot be completed in fifteen (15) working days, state the reason for the delay and the date by which the corrections will be completed. Include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Elrand, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Elrand, Compliance Officer at (425) 483-4913.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles M. Breen', with a long horizontal line extending to the right.

Charles M. Breen
District Director

cc: Daniel F. Van Dyke, Secretary/Treasurer
Van Dyke Grain Elevators, Inc.
485 Main
North Plains, Oregon 97133